

**STATEMENT OF WORK  
For Beryllium Lymphocyte Proliferation Test (BeLPT)**

**Revision Number: 0**

**Date: June 10, 2014**

**Prior SOW or Revision Date: N/A**

**1.0 Objective**

Subcontractor shall perform services in support of the Beryllium Health Surveillance Program. Subcontractor shall perform Lymphocyte Transformation/Proliferation Tests (LPT) on submitted peripheral blood specimens. Subcontractor must have a capability of testing between 2,000 and 4,000 blood specimens annually, submitted at a rate of 30 to 80 per week on average. The subcontractor must have the capability of providing a minimum of 10% additional capacity.

**2.0 Background/Introduction**

ICPT is conducting a large-scale beryllium health surveillance program of current employees. This voluntary program is conducted at the direction of the United States Department of Energy, for the purpose of identifying beryllium sensitization in current employees and cases of Chronic Beryllium Disease through the peripheral blood Lymphocyte Transformation Proliferation Test. Individuals who test positive by this test will then be offered the opportunity to participate in a more detailed clinical evaluation for the diagnosis of Chronic Beryllium Disease. A testing laboratory is being sought for purposes of conducting the LPT that will support the program of referral to other subcontract medical facilities for clinical evaluations. Clinical evaluations are not a part of this solicitation and are outside the scope of this agreement.

**3.0 Scope**

**Technical Requirements /Tasks**

The subcontractor shall perform Lymphocyte Transformation/Proliferation Tests on blood samples submitted for testing in accordance with the DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT DOE –SPEC-1142 –2001 dated April 2001 recommended method and as stated in this SOW. The subcontractor must present evidence that their laboratory understands this method. The laboratory results from the Lymphocyte Transformation/Proliferation Test (stimulation indices for known mitogens, and stimulation indices for beryllium) must be submitted in writing to the appropriate Site Occupational Medicine Medical Director within 30 days of the date that the blood specimens are received for testing.

At the time of the blood draw, individuals will be asked to complete a form that provides information including, but not limited to the following:

- 1) Name; 2) address; 3) telephone number (home and work); 4) date of birth; 5) Facility specific “employee number”, and 6) social security number. Copies of the respective information forms shall accompany blood specimens when sent to the testing laboratory so that test results can be sent to Site Occupational Medicine Medical Director.

Subcontractors are required to be open Monday thru Fridays and have the ability to receive product Tuesday thru Fridays. The subcontractor must notify the procurement administrator of plant shutdowns two weeks in advance.

#### **4.0 Submittals**

##### **Records Management**

All records acquired or generated by the subcontractor in its performance of this contract shall be the property of DOE, and therefore, shall be handled according to Site Specific Procedure and as specified in DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT), DOE –SPEC-1142 –2001 dated April 2001.

All blood specimens will be shipped in Department of Transportation approved containers via Federal Express to arrive within 24 - 30 hours of blood specimen collection. As noted previously, all shipping materials are to be provided by the subcontractor. Be advised that it is recommended that the subcontractor begin the testing of the blood specimen immediately upon receipt of the product. (Reference 6.1.1 in the DOE Specification for further guidance)

All laboratory test results must be submitted in writing to the contractor facility Occupational Medicine Medical within thirty days of receipt of the blood specimens. A fax copy is sufficient for the initial report to be followed by a written report within seven (7) calendar days. Backup data must be provided. See the format referenced in the DOE Specification Appendix B.1. Table B I, Table B II, Table B III .

In addition, the subcontractor shall provide monthly written reports providing the following information. 1) the total number of Lymphocyte Transformation/Proliferation specimens tested; 2) the total number of specimens found to have a positive Lymphocyte Transformation/Proliferation stimulation index; 3) cumulative, running totals, for the information provided in 1), 2), and 3) the time period (month) covered for the results provided in the monthly report.

Each monthly report shall be sent by facsimile and via electronic media to Occupational Medicine Department/ or designee , Building Number, by the close of the fifth business day of the month following the month in which the tests were completed.

Each monthly report shall also be mailed to the individuals listed below, by the close of the seventh business day of the month following the month in which the tests were completed according to the provisions outlined in the above paragraph.

#### **5.0 Acceptance Criteria**

Upon receipt of the acceptable laboratory test results in the format mentioned in this scope of work. The subcontractor must provide monthly invoicing to each participating facility. Code CPT 80275 for the test on the invoice.

#### **6.0 Configuration Management and Standards**

##### **6.1 Configuration Management Requirements**

There are no specific Configuration Management requirements applicable to this SOW.

##### **6.2 Applicable Standards**

Codes, Standards/ Orders/ Regulations

\*Clinical Laboratory Improvement Amendments (CLIA) accreditation

\*College of American Pathologist (CAP) accreditation

\*DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT), DOE –SPEC-1142 –2001 dated April 2001

NOTE: The following pertain to the DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT), DOE –SPEC-1142 –2001 dated April 2001 with regards to this SOW:

Exclude : “DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT), DOE –SPEC-1142 –2001 dated April 2001 with regards to this SOW: Section 7 – Tritiated thymidine BeLPT: Bronchoalveolar Lavage (BAL).

Change all reference to the word “Should” to “Shall” in the complete document.

Refer to DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT), DOE –SPEC-1142 –2001 dated April 2001 with regards to this SOW: section 9.4: ADD: “No Clinical Judgement shall be provided on the report submitted as a “Borderline”. Backup data is required to be transmitted for “Borderline” reports. The following statement is used as a reference point: “Further interpretation is required based on a more detailed evaluation of the test results, usually in combination with repeat testing...”

Add the following to the requirements listed in DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT DOE –SPEC-1142 –2001 dated April 2001 with regards to this SOW: section 6.1 – 6.3: ..... “Proper packing material as mentioned herein: Green Top Heparinized Tubes, Packing, Bubble Wrap, styrofoam box, Biohazard Shipping Box, Needles, Requisition Forms are to be provided by the subcontractor. NOTE: Material Safety Data Sheets are required to be shipped with the heparinized tubes. ”

## **7.0 ESH&Q Requirements**

### **7.1 Quality Assurance Requirements**

The Subcontractor shall follow standard commercial quality practices.

Services shall be provided in accordance with the Contractor’s Quality Assurance Program and as those called out in the DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT DOE –SPEC-1142 –2001 dated April 2001 (Section 5 ). The contractor, at mutually agreed times, shall allow access to its facility and records pertaining to this subcontract for the purpose of quality assurance audit and surveillance. An independent committee will be conducting oversight for quality and overall program compliance. An ICPT QA Evaluation team will be conducting the random Complex wide audit. This team will provide a “report card” to the subcontractor.

### **7.2 Applicable ES&H Requirements**

Hanford Site access is not authorized for work to be completed under this SOW.

### **7.3 Price-Anderson Amendments Act Requirements**

This 7.3 section and the General Provisions Article 2.11 entitled, *Price-Anderson Amendments Act (PAAA)*, are both determined to be N/A.

### **8.0 Verification/Hold Points**

There are no hold points identified for this task/

### **9.0 Reserved**

### **10.0 Work Location/Potential Access Requirements**

All analysis will be conducted and the subcontractors place of business.

### **11.0 Training**

The subcontractor is to provide training needed to keep technicians qualified to perform the blood analysis.

### **12.0 Qualifications**

The subcontractor is to provide qualified technicians per the CLIA and CAP requirements. The subcontractor is required to possess these accreditations and maintain them through the life of the agreement. The subcontractor is required to provide a Key Technical person for this subcontract. The key technical person must be a MD or PHD Immunologist point of contact. This person must be identified in advance. Any changes to this person must be submitted in writing to the procurement administrator.

### **13.0 Special Requirements**

Services shall be accomplished in accordance with all applicable laws, regulations, industry standards, and Department of Energy (DOE) Orders. The subcontractor shall utilize the latest revision of any document. The subcontractor shall use the most current version of the DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT DOE –SPEC-1142 –2001 dated April 2001 referenced in this document.

The subcontractor shall perform all work under the cognizance of the DOE Specification Beryllium Lymphocyte Proliferation Testing (BeLPT), DOE –SPEC-1142 –2001 dated April 2001 and in accordance with all applicable requirements and other applicable policies, standards, and procedures.

#### **Use of Government Vehicles**

There is no anticipated need for any Subcontractor employees to use a Government-furnished vehicle in the performance of this statement of work. The Subcontractor's employees, therefore, are specifically prohibited from driving any Government-furnished vehicles under the performance of this statement of work unless this statement of work is formally so modified by the parties and a copy of any applicable driver's license provided to the BTR.

### **14.0 Reporting/Administration**

The subcontract shall provide a monthly report which will provide the number of samples received, analyzed, and completed for that period.

### **15.0 Workplace Substance Abuse Program Requirements**

A Workplace Substance Abuse Program is not required for this SOW.